Remarks

Reconsideration of this Application is respectfully requested.

Claims 1, 3-11 and 13-35 are pending in the application, with claims 1, 11, 13, 20, 24, 26, 27, 30, 32, 34, and 35 being the independent claims. Claims 5 and 13-35 are withdrawn from consideration by the Examiner.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

The rejection of claims 1, 3, 4, and 6-11 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement is respectfully traversed. (Office Action, page 2).

The Examiner alleges that:

> The instant specification does not describe the entire genus of substances that are capable of inhibiting the claimed interaction between factors in the CD26 signaling pathway. The genus of substances capable of inhibiting the claimed interaction is vast and could encompass antibodies, small molecules, peptides as well as the described siRNA molecule. Description of a siRNA molecule capable of binding to a factor in the CD26 signaling pathway does not provide adequate written description of the infinite number of substances with the genus as instantly claimed.
>
> ***
>
> The skilled artisan would not be able to immediately envisage the substance claimed from the disclosed method.

(Office Action, pages 3-4).

Applicants respectfully disagree. The presently claimed invention is drawn to a method, i.e., a screening assay, or kit for identifying a substance that down-regulates an immune response in an animal, not a substance or a genus of substances. As such, the Examiner has failed to make a *prima facie* case of lack of written description.

The specification describes the presently claimed method, reciting the steps for identifying a substance with the desired activity. A person of ordinary skill in the art would be able to follow the detailed steps of the presently claimed method. The practice of this method requires no knowledge of the chemical structures and properties of a substance that would result in the down-regulation of an immune response; rather the presently claimed invention is the screening process, not the substances screened or the substances identified via the process. Thus, a person of ordinary skill in the art would conclude that the Applicant was in possession of the claimed invention at the time of filing. Indeed, the Examiner acknowledges the claimed screening process operates with the described siRNA molecule.

Applicants direct the Examiner's attention to Example 17 on pages 57-60 (attached hereto) of the Written Description Training Materials, Revision 1, March 25, 2008, published by the United States Patent and Trademark Office, available at http://www.uspto.gov/web/menu/written.pdf. Specifically, the Examiner's attention is drawn to the analysis of claim 2 on page 59. Clearly, based on this example and analysis, the presently claimed invention satisfies the written description requirement.

Applicants assert that the rejection of claims 1, 3, 4, and 6-11 under 35 U.S.C. § 112, first paragraph, has been overcome and respectfully request that the Examiner reconsider and withdraw the rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Example 17: Methods Using Compounds Claimed By Functional Limitations, Methods Of Identifying Compounds, And Compounds So Identified

Case Note

This example is partially based on the fact pattern in Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004).

Specification:

The specification discloses the nucleotide sequences of the coding and promoter regions of two genes that encode the human enzymes POPKIN-1 and POPKIN-2, and a comparison of those sequences. The specification characterizes the enzymatic activity of POPKIN-1 and POPKIN-2 as the same activity. The specification also describes how to make cells that express either POPKIN-1 or POPKIN-2, but not both. The specification describes assays using these cells to screen for compounds which selectively inhibit the expression or activity of POPKIN-2 but not POPKIN-1. "Selective inhibition" is defined as the ability to inhibit POPKIN-2 activity but not POPKIN-1 activity. The specification describes methods of treating specified diseases characterized by aberrant POPKIN-2 activity, using compounds to be identified in screening assays to selectively inhibit POPKIN-2. There are no known compounds that selectively inhibit POPKIN-2 and none are disclosed in the specification.

Example 17: Compounds Claimed By Function

Claims:

Claim 1: A method for selectively inhibiting POPKIN-2 activity in a patient, comprising administering a compound that selectively inhibits activity of the POPKIN-2 enzyme.

Claim 2: A method for identifying a compound that selectively inhibits POPKIN-2 activity comprising

(a) contacting a test compound with a cell expressing POPKIN-2 but not POPKIN-1 and measuring POPKIN-2 activity,

(b) comparing the measured activity from step a to the activity of POPKIN-2 in a non-contacted control cell,

and if the measured activity of step a is less than the measured activity of POPKIN-2 in the control cell then,

(c) contacting the compound with a cell expressing POPKIN-1, but not POPKIN-2 and measuring POPKIN-1 activity, and

(d) comparing the measured POPKIN-1 activity from step c to the activity of POPKIN-1 in a non-contacted control cell,

wherein, if the measured POPKIN-1 activity of contacted and control cells is the same, a compound that selectively inhibits POPKIN-2 is identified.

Claim 3: A compound identified by the method of claim 2.

Analysis:

Claim 1

A selective POPKIN-2 inhibitor is required to practice the invention.

The specification does not describe an actual reduction to practice of a method of selectively inhibiting POPKIN-2 using a compound that selectively inhibits POPKIN-2 activity. The specification also does not describe the complete structure of a compound that selectively inhibits POPKIN-2 activity. Further, the specification does not describe the partial structures, or physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity.

While the specification describes the amino acid sequences of POPKIN-1 and POPKIN-2, the specification does not describe any correlation between the sequences and the structure of any compounds that would selectively inhibit POPKIN-2 activity.

The specification describes a method of screening compounds for selective inhibition of POPKIN-2 activity; however, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity. Thus, the specification does not disclose a correlation between selective inhibitory activity and the structure of a putative inhibitor.

Example 17: Compounds Claimed By Function

The level of skill and knowledge in the art is that there are no known compounds that selectively inhibit POPKIN-2 and no known correlation between any structural component and the ability to selectively inhibit POPKIN-2. Thus, the disclosure does not allow one of skill in the art to visualize or recognize the structure of any compound required to practice the claimed method. Accordingly, one of ordinary skill in the art would conclude that the applicant would not have been in possession of the claimed method of selectively inhibiting POPKIN-2 activity because a compound possessing the desired activity required to practice the method is not adequately described and was not known in the art.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

Claim 2

The claim is drawn to a screening assay for identifying compounds that selectively inhibit the activity of POPKIN-2, but not POPKIN-1. The claim does not limit the compounds that may be used in the assay.

The specification does not describe the complete structure, partial structures, physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity, nor does the specification describe any correlation between the sequences of POPKIN-1 and POPKIN-2 and the structure of any compounds that would selectively inhibit POPKIN-2 activity. The specification does describe the claimed method of screening compounds for selective inhibition of POPKIN-2 activity, reciting the instant steps for identifying a compound with the desired activity.

The level of skill and knowledge in the art is such that one would be able to follow the detailed steps of the claimed method. The practice of the method requires no knowledge of the structures and properties of a compound that would predictably result in the desired activity; rather the claimed invention is the screening process, not the compounds screened or the compounds identified via the claimed process. Thus, one of ordinary skill in the art would conclude that the applicant would have been in possession of the claimed method for identifying compounds that selectively inhibit POPKIN-2 activity at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 2.

Claim 3

The claim is drawn to a selective POPKIN-2 inhibitor. The claim encompasses a genus, in which all potential members share a functional activity, *i.e.,* selective inhibition of POPKIN-2.

Example 17: Compounds Claimed By Function

The number of structures encompassed by the claim may be vast or conversely there may be no structures that possess the claimed function.

The specification does not describe the complete structure of a compound that selectively inhibits POPKIN-2 activity. The specification also does not describe the partial structures, or physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity.

While the specification describes the amino acid sequences of POPKIN-1 and POPKIN-2, the specification does not describe any correlation between the sequences and the structure of any compounds that would selectively inhibit POPKIN-2 activity. The specification describes a method of screening compounds for selective inhibition of POPKIN-2 activity; however, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity. Thus, the specification does not disclose a correlation between selective inhibitory activity and the structure of a putative inhibitor.

The level of skill and knowledge in the art is such that one would be able to follow the detailed steps of the disclosed method, however, claim 3 is drawn to a product, not a method. The claim extends beyond what is disclosed (*i.e.*, is a so-called "reach through" claim). Given that there is no known correlation between any structural component and the ability to selectively inhibit POPKIN-2, the specification's description of a screening method does not correlate to a structural description of the resulting products. Thus, while one of ordinary skill in the art would conclude that the applicant would have been in possession of the claimed method for identifying compounds that selectively inhibit POPKIN-2 activity, one of ordinary skill in the art would not conclude that the applicant would have been in possession of any compounds having the desired activity at the time of filing.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.